Empi

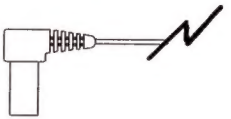
EPIX VT™

■ Dual Channel Transcutaneous Electrical Nerve Stimulator

Instruction Manual

Additional System Information

Epix VT™ requires the use of Empi lead wires with the custom safety connection as pictured below.



Instruction Manual for the Empi EPIX VT™ TENS Device

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Introduction

What is Pain?

Pain is an unpleasant sensation that can serve a useful purpose by alerting us to a possible or actual injury or disease. When the body is functioning normally, pain serves as a warning system that something is not right. Without pain a person would not know when to get away from danger or seek medical help. Pain becomes a problem when it continues after treatment has started or long after an injury is healed.

There are two types of pain: acute and chronic. Acute pain is limited in duration. Typical examples are sprains, incisional pain or muscle strain. This type of pain is typically associated with workplace or recreational injuries. Chronic pain, however, is a long-lasting, persistent pain that ceases to serve as a warning system and becomes a problem. TENS was developed to help relieve some types of both chronic and acute pain.

What is TENS?

TENS stands for Transcutaneous Electrical Nerve Stimulation. Pain, whether chronic (long-term) or acute (short-term), can be relieved through a variety of methods, including drugs, topical ointments, surgery and electrical stimulation. TENS devices deliver electrical pulses through the skin to the cutaneous (surface) and afferent (deep) nerves to control pain. Unlike drugs and topical ointments, TENS does not have any known side effects.

How Does TENS Control Pain?

There are two major theories as to how electrical stimulation relieves pain. According to the "gate control theory," pain and non-pain impulses are sent to the brain from the local nervous system. These pulses travel through the cutaneous nerves to the deeper afferent nerves and then to the spinal cord and brain. Along the path are many areas referred to as "gates." These gates control which impulses are allowed to continue to the brain. The gates prevent the brain from receiving too much information too quickly. Since the same nerve cannot carry a pain impulse and a non-pain impulse simultaneously, the stronger, non-pain impulse (from the TENS device) "controls the gate."

According to the second theory, TENS stimulation encourages the body to produce natural pain killers called endorphins. These chemicals interact with receptors, blocking the perception of pain. This is similar to the way the pharmaceutical drug morphine works, but without the side effects associated with morphine.

No matter which pain theory is applied, TENS has been proven useful in pain management. By reading this manual and carefully following the treatment instructions given to you by your clinician, you will attain the maximum benefit from your TENS device.

■ Patient Selection

⚠ Indications

TENS devices are indicated for:

- Symptomatic relief and management of chronic, intractable pain.
- Adjunctive treatment for post-surgical and post-trauma acute pain.

⚠ Contraindications

TENS treatments should not be used if the patient has any of the following conditions:

- Undiagnosed pain (until the etiology is established).
- Demand-type implanted pacemaker or defibrillator.
- Transcerebral electrode placements.
- Electrode placements over the carotid sinus (neck) region.

⚠ WARNINGS

Review the following warnings before initiating treatment:

- **Pregnancy** - The safety of TENS devices for use during pregnancy or delivery has not been established.
- **Symptomatic Treatment** - TENS is a symptomatic treatment and, as such, may suppress the sensation of pain that would otherwise serve as a protective mechanism.
- **Central Pain** - TENS is not effective for pain of central origin.
- **Non-curative** - TENS has no known curative value for the conditions for which it is indicated.
- **Medical Supervision** - TENS should only be used under the medical supervision of a physician or a medical practitioner to whom the patient is referred by the physician. TENS is a prescription device and should not be given to other individuals.
- **Children** - Keep out of the reach of children.
- **Electromagnetic Radiation** - The TENS lead wires and electrodes should be removed before using industrial, scientific or medical equipment (Group 2 ISM) that intentionally generates high frequency or high energy electromagnetic radiation. Operation in close proximity (e.g. < 3m) to this equipment may startle the user by producing output instability or improper operation of the stimulator. Simultaneous connection to the TENS user may result in burns and possible damage to the stimulator. Examples of Group 2 ISM Equipment are: radio-frequency (rf) induction heating, cutting or welding equipment and short-wave/microwave therapy and diagnostic equipment such as diathermy or surgical electrocautery units.
- **External Defibrillators** - Remove the TENS electrodes before defibrillation signals are applied. Defibrillation of a person wearing a TENS device can damage the device whether it is turned on or off. Under some circumstances there can be risk of burns under the electrode sites during the defibrillation.
- **Wall Sockets** - Do not plug lead wires into AC power outlets such as wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether or not the lead wires are attached to the stimulator.

Warnings *continued*

- **Patient Monitoring Equipment** - TENS devices may interfere with the intended operation of electronic monitoring equipment (such as ECG monitors or ECG alarms) if the stimulator is simultaneously connected to the patient being monitored.
- **Safety and Efficacy** - The safety and efficacy of TENS depends on the proper use and handling of the device and accessories. IF USED IMPROPERLY, TENS HAS A POTENTIALLY HAZARDOUS ELECTRICAL OUTPUT. IT MUST BE USED ONLY AS PRESCRIBED. Electrode or lead wire burns may result from misuse. Electrodes and lead wires should be securely fastened to prevent inadvertent disconnection. Electrodes and lead wires will eventually wear out. Check accessories regularly for signs of wear, and replace if needed.

⚠ Precautions

Review the following precautions:

- **Prescribed Conditions** - TENS therapy should not be used for conditions other than those for which the device is prescribed. If there are any changes in an existing condition, or if a new condition develops, the patient should consult a clinician.
- **Patient Selection** - The efficacy of TENS therapy is highly dependent upon patient selection by a person qualified in the management and treatment of pain.
- **Drugs or Mental State** - Treatment outcome will be influenced by the patient's psychological state and use of drugs.
- **Sensitivity to Stimulation** - Patients who react negatively to the stimulation sensation after an adequate trial period or who find stimulation intolerable should not undergo further TENS treatment.
- **Sensory Deprivation** - Due to the risk of adverse skin reactions, electrodes should not be placed on areas of skin with reduced response to normal sensory stimuli.
- **Skin Irritation** - Skin irritation, hypersensitivity and burns beneath electrodes have been reported with the use of TENS. Electrodes should not be left in place for long periods of time without checking or cleaning the skin underneath them. Electrode sites should be rotated with long term use when possible. DO NOT CONTINUE STIMULATION OVER IRRITATED SKIN. Consult a clinician if any skin irritation or reaction develops at the electrode sites following use of the stimulator. The clinician may recommend a different type of electrode.
- **Operating Machinery** - Do not operate hazardous equipment such as automobiles or power tools while using TENS. Abrupt changes in sensation can occur during the use of TENS which could startle the patient and create a hazard.
- **Cellular (Wireless) Telephones and Two Way Radios** - Avoid operation in close proximity (e.g. < 1m) to transmitting cellular (wireless) telephones or two-way radios. This equipment may produce instability in the stimulator output. Sudden, unexpected changes in output could startle the patient and create a hazard.

Precautions *continued*

- **Water Immersion** - Do not use in the bath or shower. The stimulator should not be submerged in water or other liquids as this may startle the patient and possibly damage the stimulator. If the device should become accidentally immersed in water, do not attempt to use it immediately afterward. Remove the battery and allow the excess water to drain away. Air dry the device thoroughly for at least 48 hours at room temperature before attempting to operate it.
- **Heat and Cold** - The use of heat or cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair the performance of the electrode or alter the patient's circulation/sensitivity and increase the risk of injury to the patient.
- **Sleep** - Do not use while sleeping because the lead wires or the electrodes may become disconnected.
- **Electrodes and Lead Wires** - Do not use electrodes and lead wires other than those supplied with the system or recommended by Empi. The safety of other products has not been established, and their use could result in injury to the patient. NOTE: An electrode active area of no less than 1.6cm (0.25in) is recommended for the Epix VT.
- **Batteries** - Do not carry batteries in a pocket, purse or any other place where the terminals could become short-circuited, e.g. by way of a coin or paper clip. Intense heat could be generated and injury may result.
- **Battery Charger's** - Only the Empi battery charger should be used with Empi rechargeable batteries. Do not attempt to recharge any battery other than the rechargeable battery supplied by Empi for this device. Attempts to charge alkaline or other non-rechargeable batteries could cause the battery to overheat, burst or be permanently damaged.

⚠ Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of TENS.

Product Description

The Epix VT™ is a dual channel TENS device with twelve (12) program options. All the operation modes produce the unique Bi-Sourced© waveform to deliver energy efficiently through the cutaneous tissues.

The Epix VT TENS system components and accessories may include:

- Epix VT TENS Device
- User's Manual
- Electrodes
- Lead Wires
- Batteries (either rechargeable or alkaline)
- 110V/60Hz Battery Charger (if rechargeable batteries are used)

Stimulator Controls and Features

Become familiar with the location of the features of the Epix VT TENS device before initiating treatment. Figure 1 outlines the Channel Output Jacks, the combined Battery Status and ON/OFF Indicator Lights, the Intensity Controls, the Program Option Controls, the Descriptive Pain Scale and the Data Retrieval Controls.

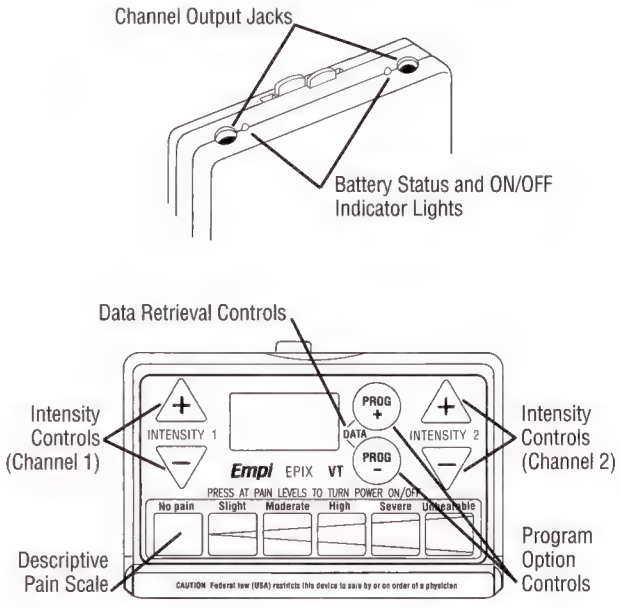


Figure 1.

Channel Output Jacks

There are two Safety Jacks labeled "1" and "2" (Figure 1). These jacks allow lead wires to be connected to the TENS device. Channels 1 and 2 operate independently.

ON/OFF and Battery Status Indicator Lights

The ON/OFF Indicator Lights indicate that the device is operational. The intensity and rate of flash changes with the output intensity and rate. As the intensity of the stimulation is increased, the intensity of the light also increases. (Above 40 pps the light will appear to be on continuously.) These lights also indicate that the battery voltage is low. The status lights will flash at a different pace if the battery voltage is at or below 7.0 volts. The device will automatically shut off if the battery voltage falls to 5.4 volts. When the battery status light pattern begins, it is recommended that the battery be changed as soon as possible.

Descriptive Pain Scale

The Epix VT device offers a Descriptive Pain Scale for determining the patient's perceived level of pain before and following the TENS application. The device is turned on by depressing the description that best represents the patient's pain. To turn the device off, the level of pain at that time is selected and depressed.

Intensity Controls

Epix VT amplitude is adjustable from 0-60 milliamperes. The intensity (amplitude and pulse duration) of the stimulation available through each of the lead wires attached to either or both of the channels is controlled by the push buttons on the control panel (see Figure 1). Depressing the up-arrow button increases the intensity of the stimulation. When increasing intensity,output will be delivered continuously. Decreasing the intensity level is done by depressing the down-arrow. Increasing or decreasing intensity adjusts amplitude and pulse duration simultaneously.

Note: THE INTENSITY CONTROLS DO NOT TURN THE DEVICE ON AND OFF. THIS IS ACCOMPLISHED BY DEPRESSING ONE OF THE PAIN LEVELS INDICATED ON THE PAIN SCALE. INTENSITY WILL BE RESET TO ZERO EACH TIME THE DEVICE IS TURNED OFF.

Program Option Controls

Epix VT offers twelve (12) program options. Selecting a specific program option is done by depressing one of the PROG buttons (Figure 1). The "PROG +" and "PROG –" buttons allow going forward or backward when selecting the program option.
A description of the available program options is described in the Program Options section of this manual.

1	Extremely low frequency	ELF
2	Dual pulse	DP
3	High frequency	HF
4	Bi-modal	BM
5	Ramped burst	RB
6	Alternating ramped burst	ARB
7	Amplitude modulation	MA
8	Random modulation	RM
9	Continuous	C
10	Cycled burst	B
11	Rate modulation	R
12	Multi-modulation	M

Battery Compartment

The Battery Compartment is located under the Front Panel Cover (Figure 2). See Changing the Battery section for instructions on inserting or replacing the battery.

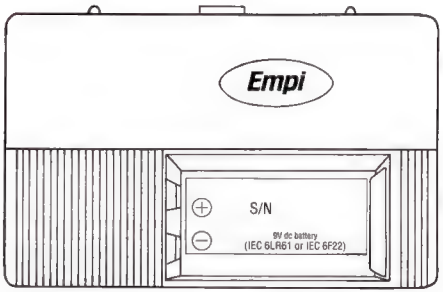


Figure 2. Battery Compartment

Belt Clip

The Belt Clip allows you to wear the TENS device on a belt or pants top. If the Belt Clip is not already attached, securely attach it to the device. Open the lid past the first stop, slide the Belt Clip on the bottom of the lid to fit the groove, pull it up until it engages on the bottom and snap the top catches over the top of the lid.

Covers

There are two covers for the Epix VT TENS device. The Control Panel Cover rotates on and off the Control Panel (Figure 3). The Belt Clip is attached to this cover to allow the user to open the device and adjust the controls while the device is being worn.

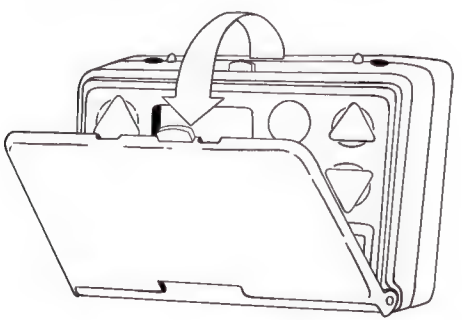


Figure 3. Opening the Control Panel Cover

The Battery Compartment Cover is on the front of the device (Figure 4). It is opened and closed using the "thumb print" depression to slide the cover on and off the device.

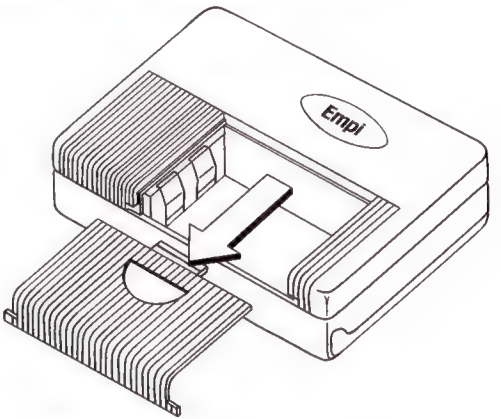
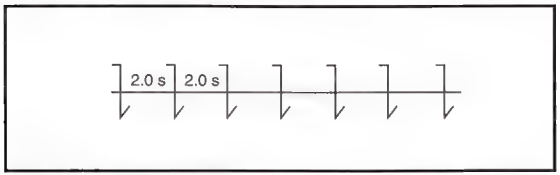


Figure 4. Opening the Battery Compartment Cover

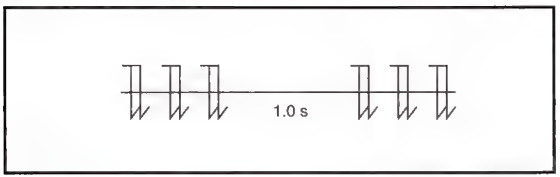
Program Options

1 Extremely Low Frequency (ELF)



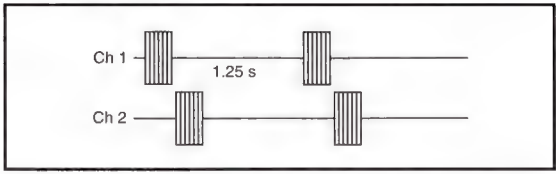
With the Extremely Low Frequency program, the TENS stimulator delivers one pulse every two seconds from both channels simultaneously.

2 Dual Pulse (DP)



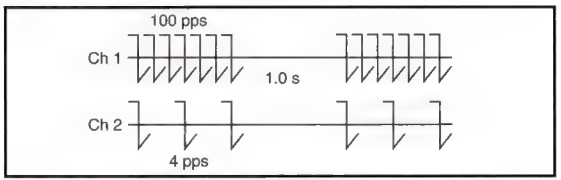
The Dual Pulse program is similar to the conventional burst mode. Two pulses, separated by 3 milliseconds, are delivered at the rate of 20 pps for 1.0 second, followed by no stimulation for 1.0 second. The pulses are delivered through both channels simultaneously.

3 High Frequency (HF)



The High Frequency program is a 2500 pps burst for 0.25 second, followed by 1.25 seconds of no stimulation. Channel 2 alternates with Channel 1.

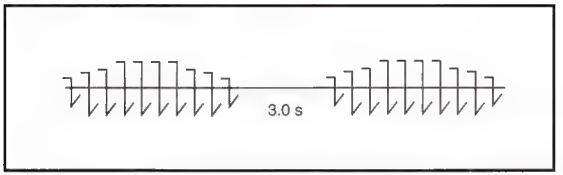
4 Bi-modal (BM)



In the Bi-modal program, Channel 1 delivers the pulse at 100 pps and Channel 2 delivers the pulse at 4 pps. The stimulation is cycled 1.0 second on, 1.0 second off. Both channels deliver stimulation simultaneously.

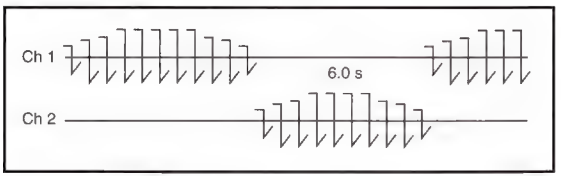
Program Options *continued*

5 Ramped Burst (RB)



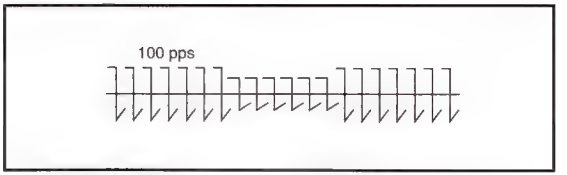
The Ramped Burst program gradually increases the intensity from 0 to the set level over 0.4 second, maintains it at the set level for 1.0 second, and then gradually decreases the intensity over 0.5 second. The device then sends no stimulation for 3.0 seconds. The rate is set at 100 pps. The pulses are delivered through both channels simultaneously.

6 Alternating Ramped Burst (ARB)



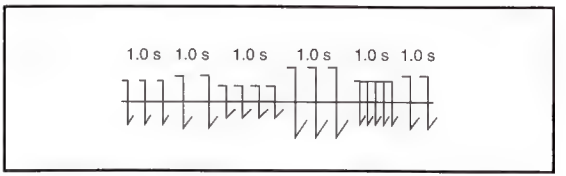
The Alternating Ramped Burst program is the same as the Ramped Burst, but Channel 2 starts after Channel 1 has completed a cycle. Channel 1 gradually increases intensity from 0 to the set level over 0.5 second, holds at the set intensity for 5.0 seconds, and then decreases intensity over 0.5 second. Channel 1 then stays off for 6.0 seconds. As Channel 1 intensity is decreasing, Channel 2 starts increasing intensity, via the same pattern. The set rate is 100 pps.

7 Modulated Amplitude (MA)



In the Modulated Amplitude program, for 0.5 second the intensity is at 100% of the set level and the next 0.5 second, it is at 60%. The cycle is then repeated. There is no off time. The rate is 100 pps. Both channels are used simultaneously.

8 Random Modulation (RM)

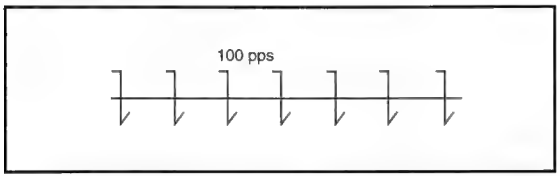


Rate is selected pseudo-randomly from 8 rates - 2, 10, 20, 40, 60, 80, 100, 150 pps; pulse duration is selected pseudo-randomly from 7 values between 50% of set pulse duration and set pulse duration. Each combination is on for 1 second.

Program Options *continued*

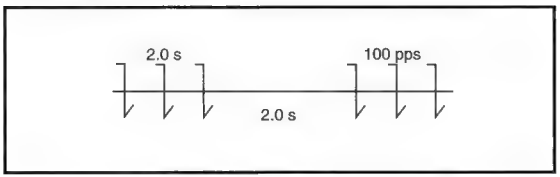
Adjustable Rate Options:
The following program options (9-12) offer adjustable rate. To change rate, press both PROG+ and PROG- buttons at the same time while device is on and set on one of the rate adjustable program options (9, 10, 11, or 12). Display will show the program letter (C, B, R, or M) and the current rate. Use PROG+ or PROG- to go to the next or previous rate. Press PROG+ and PROG- buttons at the same time when selection is complete. Automatic return to program operation will occur after one minute.

9 Continuous (C)



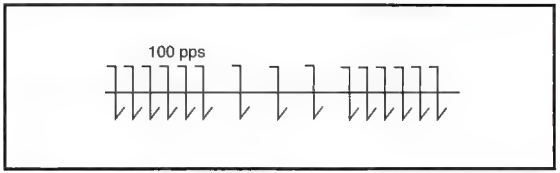
This setting produces a continuous stimulation at the set intensity and a rate of 100 pps.

10 Cycled Burst (B)



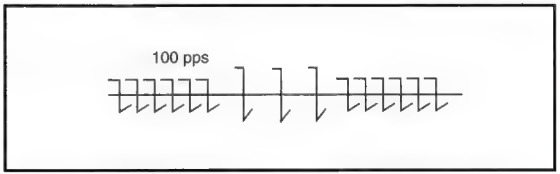
In the Cycled Burst program, stimulation is on for 2 seconds and off for 2 seconds.

11 Rate Modulation (R)



In the Modulated Rate program, for 0.5 second the rate is at 100 pps and for the next 0.5 second, it is at 50 pps. The cycle is then repeated. There is no off time. Both channels are used simultaneously.

12 Multi-modulation (M)



In the Multi-modulated program, for 0.5 second the rate is at 100 pps and the intensity is at 60% of set level and for the next 0.5 second, the rate is at 50 pps while the intensity is at 100% of set level. The cycle is then repeated. There is no off time. Both channels are used simultaneously.

Data Retrieval Controls

The Epix VT device stores usage and pain scale data. This feature is for clinician use only.

General Operation

Just as pain is an individual sensation, so is pain relief. Pain relief regimens vary from person to person. Some patients may experience pain relief by using the device for only a few minutes a day. In some cases, continuous use of TENS may be required to control pain. Sometimes complete pain relief is not achieved immediately, but improves with time. Your clinician will help you determine the treatment regimen or program that is right for you. TENS should be used only under a clinician's directions.

Electrode Selection and Care

The Epix VT TENS device provides the best results when used with Empi electrodes and accessories. A variety of these products are available for your convenience. Your clinician or authorized Empi representative can help you select the appropriate products. To avoid skin irritation and ensure good contact with your skin, care for the electrodes as instructed on the electrode package. Care will vary with the type of electrode.

Initiating Treatment

STEP 1: Prepare the Skin

Before attaching the electrodes, identify those areas where your clinician has recommended electrode placement. Wash the area gently with mild soap and water, then rinse and dry the area thoroughly. (The use of rubbing alcohol is discouraged except where necessary to decrease excessive oils on the skin.) It may be necessary to trim excess body hair with scissors prior to applying the electrodes. Do not shave the area immediately before beginning treatment. Wait 24 hours after shaving an area before initiating treatment at that site. Failure to adequately prepare the skin may cause improper adhesion or skin irritation and provide less than ideal stimulation.

Note: Skin is not accustomed to exposure to the electrode gel and adhesives used with TENS. While Empi takes great care and tests all electrode materials to avoid problems, irritation may appear as redness, small pimple-like lesions, or blisters. If your skin develops any persistent redness or irritation, do not continue to apply the electrodes to the same area. Discuss this with your clinician or call your Empi representative.

STEP 2: Connect the Lead Wires to the Electrodes

Connect the lead wires to the electrodes before applying the electrodes to the skin. This will reduce the possibility of dislodging the electrodes.

STEP 3: Attach the Electrodes

Place the electrodes on the skin as recommended by your clinician. Generally, the electrodes should be at least two inches apart; however, your clinician will work with you to determine the most effective electrode placement. The electrodes should be comfortable to wear and should be placed exactly where you have been shown. The most common problems with TENS therapy are caused by failure to wear the electrodes as directed.

Initiating Treatment *continued*

STEP 4: Turn On the Device

Turn on the Epix VT by depressing the button on the Pain Scale that best describes your current level of pain. Current control settings will be displayed on the Control Panel.

STEP 5: Select the Treatment Settings

Your clinician has recommended one of the program options explained in the Stimulator Controls and Features section of this manual. Set the device to the recommended setting if different from the one shown on the display.

Note: To avoid a startling effect, turn the TENS device off before adjusting the settings.

Note: Consult your clinician before changing the recommended settings.

STEP 6: Connect the Lead Wires to the Device

Caution: Always turn the TENS device off before connecting the lead wires to the device.

Push each lead wire connector into its corresponding Channel Output Jack located on the top of the device. The Channel Output Jack marked "1" is controlled by the Channel 1 Intensity Controls; the jack marked "2" is controlled by the Channel 2 Intensity Controls. If you only want to stimulate using one channel, you will need only one lead wire. Connect this single lead wire into either Channel Output Jack (Figure 5.)

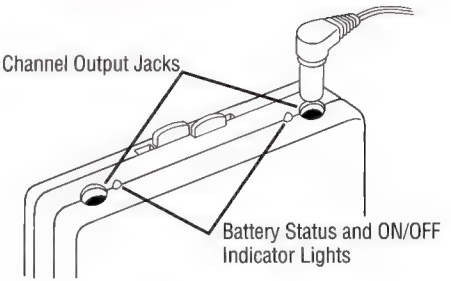


Figure 5. Connecting the Lead Wires

Note: Use care when you connect and disconnect the lead wires from the electrodes and the device. Pulling on the lead wire instead of its insulated connector may cause lead wire breakage.

STEP 7: Begin Treatment

Depress the Channel 1 and Channel 2 Intensity Controls until the stimulation is strong but tolerable. It is important that you can feel the stimulation.

The ON/OFF Indicator Lights should be on. If the ON/OFF Indicator Lights do not come on, or if they alternately turn on and off at a rapid pace, the battery needs to be changed. The display will also indicate low battery status.

Caution: Always turn the TENS device off when changing the battery.

Initiating Treatment *continued*

The output of the device may decrease slightly during stimulation as the battery wears down. If this happens, you may need to increase the intensity slightly to maintain adequate stimulation.

STEP 8: Record Treatment

Before turning off the TENS device, you may want to record the location of the electrodes, the settings of all controls and any progress achieved. Good record keeping will help when resuming treatment or reviewing progress with your clinician. If after several treatments you do not achieve pain relief, consult your clinician for new electrode placement or stimulation program alternatives.

STEP 9: End Treatment

Enter your current pain level on the pain scale when treatment is complete. Then disconnect the lead wires, grasping them by the insulated connector, not the lead wire.

Remove the electrodes carefully from your skin, peeling them off gently in the direction that body hair lies. The electrodes may be left in place if treatment will be resumed shortly.

After the electrodes are removed, clean the skin thoroughly with mild soap and water. For electrode storage and care, refer to electrode packaging for instructions.

Changing the Battery

The TENS device is powered by a single battery. For best results, use Empi rechargeable or 9 Volt alkaline batteries. When replacing alkaline batteries, we recommend the use of Eveready Energizer model 522, or Varta brand model 4022. If your kit includes rechargeable batteries, see the Charging the Battery section of this manual for directions.

Change the battery when the low battery indicator light pattern occurs, or if the device will not turn on. See Battery Information in the Technical Section of this manual for the typical life of your alkaline or rechargeable battery. Actual battery life will depend upon the battery type, skin impedance, electrode type and device settings used.

Caution: Turn device off and disconnect the electrode lead wires before inserting a fresh battery.

1. Slide the battery compartment cover off the unit.

2. Remove the discharged battery from the unit by lifting the ribbon.

3. Place the new battery into the space provided (Figure 6). Be sure the terminals are in proper alignment. The "+" of the battery should be at the "+" terminal of the device and the "-" of the battery should be at the "-" terminal. Do not force the battery. If force is required, you may be putting the battery in backwards. Check the "+" and "-" markers.

Changing the Battery *continued*

Caution: Inserting the battery incorrectly may cause the battery to rupture or generate intense heat if allowed to remain in the incorrect position. This may cause irreversible damage to the battery. If there are signs of this type of damage, discard or recycle the battery and order a replacement.

Ni-Cd

The proper disposal of rechargeable batteries may be regulated in your area. Contact your local waste management official for information regarding the environmentally sound collection, recycling and disposal of these batteries.

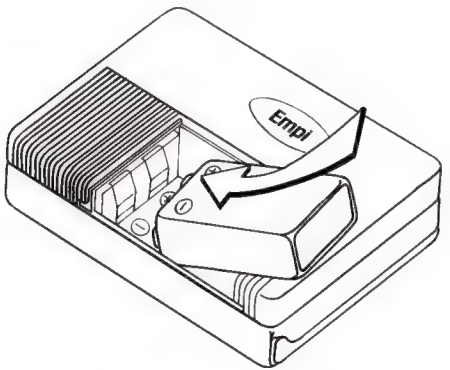


Figure 6. Battery Compartment

Charging the Battery

If you purchased a rechargeable battery system, you will typically charge one battery while using the other. If the Low Battery Indicator flashes, recharge the battery as soon as possible.

Caution: Do not attempt to charge alkaline batteries or any battery other than an Empi rechargeable battery.

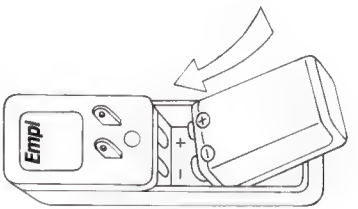


Figure 7. Battery Charger

1. Place the battery in the charger (Figure 7). The battery should slide in easily. If force is required, you may be putting the battery in backwards. Check the "+" and "-" markers.

Caution: The battery may overheat and rupture if it is inserted backwards.

2. Plug the charger into any standard 110V/60Hz outlet. The battery should be fully charged within 14 hours.

■ Troubleshooting and Repair

Troubleshooting

If the TENS device does not function:

1. Make sure the battery is properly installed and the battery contacts are clean. Be sure to observe proper polarity markings when replacing the battery.

2. If the Status Lights are alternately flashing in a rapid on/off pattern or the battery status symbol shows on the display, replace the battery.

3. If the Indicator Lights are showing normal operation (not low battery status) and you feel no stimulation, check that the lead wires are properly connected and the electrodes are still in place. If the unit appears to be functioning, but there is no stimulation, the lead wires or electrodes may need to be replaced.

4. If the battery appears to be charged and the stimulator is not functioning, turn both Intensity Controls to zero. Then gradually increase the stimulation.

5. If the device does not seem to be saving data correctly, make sure that amplitude used was greater than 5mA.

6. If display is not visible, check that unit is turned on and battery is charged. See Repair Section if needed.

Repair

There are no user serviceable parts inside the stimulator. If the unit appears to be non-functional, call the Empi Service Center at 1-800-862-2343 for instructions.

In the case of repairs or returns outside of North America, notification and return shipment should be sent to an Empi Authorized Service Center. To locate the appropriate Service Center outside of North America, contact your Authorized Empi Distributor, or contact Empi directly at 1-651-415-9000.

■ Maintenance, Cleaning, Storage and Disposal

Maintenance

Check periodically for signs of wear or damage such as cracked insulation on lead wires, and replace these items as they wear out.

Under normal conditions, the stimulator does not require periodic maintenance or calibration; however, if it becomes necessary to perform periodic safety checks, all the necessary information is included in the Technical Information section of this manual. These checks should be performed by a qualified technician.

Cleaning

Cleaning the Stimulator: Use a cloth moistened with soap and water to clean the exterior of the device. Use of other cleaning solutions may damage the case. Never immerse the device in water or other liquids.

Cleaning the Battery Contacts: Gently clean the battery contacts using a cotton-tipped swab soaked in rubbing alcohol. Do not use sandpaper or other abrasive material.

Cleaning the Lead Wires: Periodically wipe the lead wires clean with a cloth dampened in a mild soap solution, then gently wipe them dry. Use of rubbing alcohol on the lead wires will damage the insulation and dramatically shorten their life.

■ Maintenance, Cleaning, Storage and Disposal *continued*

Storage

To properly store the stimulator for an extended period of time, i.e. 90 days or more, remove the battery from the stimulator and store the stimulator in a dry location.

Disposal

Ship the stimulator or rechargeable battery, postage prepaid, to the Empi Service Center for proper disposal or recycling of that item. Please enclose a note indicating that the item is being returned for disposal or recycling. Outside of North America, contact your Authorized Empi Distributor, or contact Empi directly at 1-651-415-9000.

Physical Characteristics

Standard Measurement Conditions 23°C, 1kΩ Resistive load, 8.4V d.c. supply voltage

Waveform Balanced asymmetrical biphasic; nominally constant voltage positive phase and constant current negative phase over the AAMI load range of 200 to 1kΩ. 20% tolerance unless stated otherwise. See Figures B and C.

Standard Measurement

	Output	See Figure
Both Phases (Vpp)*	0 to 60V	A
1kΩ resistive (Ipp)*	0 to 60mA	A

*Vpp = Volts peak to peak *Ipp = mA peak to peak

Pulse width* Adjustable; 0 to 400 µs at 50% peak amplitude. See Figure A.

*Determined by the intensity setting.

Maximum Current

Absolute Average Value: 10 mA into 500Ω
Root Mean Square: 10 mA into 1kΩ
Electrode Surface Area 1.6 cm^2 minimum area recommended.

Program Options (PPR™)	Parameters
1 Extremely Low Frequency (ELF)	Rate = 0.5 pps, continuous output.
2 Dual Pulse (DP)	Rate = 20pps, 2 pulses, time between leading edges = 3.0 ms, burst mode, on time = 1s, off time = 1s.
3 High Frequency (HF)	Rate = 2.5 kHz, burst mode, on time = 0.25s, off time = 1.25s, Channel 2 on time to follow Channel 1 on time.
4 Bi-modal (BM)	Channel 1 rate = 100 pps, Channel 2 rate = 4 pps, burst mode, on time = 1s, off time = 1s.
5 Ramped Burst (RB)	Rate = 100 pps, ramp up time = 0.5 s, on time = 1s, ramp down time = 0.5s, off time = 3s. Ramp up starts from 0.
6 Alternating Ramped Burst (ARB)	Rate = 100 pps, ramp up time = 0.5s, on time = 5s, ramp down time = 0.5s, off time = 6s, Channel 2 follows Channel 1, Channel 2 ramp up starts at the end of Channel 1 ramp down. Ramp up starts from 0.
7 Amplitude Modulation (MA)	Amplitude modulation is done through pulse width modulation. Rate = 100 pps, modulation rate = 1.0 pps duty cycle = 50%, depth of modulation = -40%.

Program Options (PPR™)	Parameters
8 Random Modulation (RM)	Rate is selected pseudo-randomly from 8 rates - 2, 10, 20, 40, 60, 80, 100, 150 pps; pulse width is selected pseudo-randomly from 7 values between 50% of set pulse duration and set pulse duration. Each combination to be on for 1s.
9 Continuous (C)	Preset rate = 100 pps, adjustable (2, 10, 20, 40, 60, 80, 100, 150 pps), continuous at set intensity.
10 Cycled Burst (B)	Preset rate = 100 pps, adjustable (2, 10, 20, 40, 60, 80, 100, 150 pps), on time = 2s, off time = 2s.
11 Rate Modulation (R)	Preset rate = 100 pps; adjustable (2, 10, 20, 40, 60, 80, 100, 150 pps). modulation rate = 1.0 pps, duty cycle = 50%, depth of modulation = -50%.
12 Multi-modulation (M)	Preset rate = 100 pps; adjustable (2, 10, 20, 40, 60, 80, 100, 150 pps), modulation rate = 1.0 pps, duty cycle = 50%, depth of modulation, Pulse duration = -40% when rate is not modulated, Rate = -50% when pulse duration is not modulated.

To Select Rate for Program Options 9, 10, 11, and 12

To Initiate	Press PROG+ and PROG- buttons together while device is on in the appropriate program option (9, 10, 11 or 12). Display will show the PPR letter (C, B, R, or M) and the current rate.
To change	Use PROG+ or PROG- button to go to the next or previous rate.
To Exit	Press PROG+ and PROG- buttons together. Automatic exit will happen after 1 minute and display will show the PPR number.

Data Retrieval

To Initiate	Press PROG+ and PROG- buttons together. Power up the device using any pain scale button. Display will show DATA along with the first data value.
To Advance	Use PROG+ or PROG- button to see the next or previous data.
To Exit	Shut the device off using any pain scale button.
To Clear Data	With PROG - button pressed, press PROG + button. Display will show "CL". Press PROG + button again (PROG - button is still pressed) to clear data or release both buttons to leave the data as is.

Data Codes

P	Percentage of sessions with pain relief.
S	# of sessions (maximum 255). Only counts sessions where intensity is ≥ 5mA.
L	Average session length (hours and minutes; + or – 1 minute).
D	Most frequent degree of change in pain relief from 1 to 5 (e.g. a pain rating of high (4) when treatment is initiated and a pain rating of slight (1) when the treatment is terminated is scored as a 3 degree change in pain relief). This applies to sessions that recorded pain relief.
Ch1	Most frequently used intensity range for Ch1 (0-5mA, 6-20mA, 21-40mA, 41-60mA).
Ch2	Most frequently used intensity range for Ch2 (0-5mA, 6-20mA, 21-40mA, 41-60mA).

Audio Feature

This device may or may not have a buzzer feature. If the serial number on your device is higher than 3123750, it does not have the audio feature. If the serial number of your device is 3123750 or lower, you have this feature. To enable or disable this feature, power up the device using Descriptive Pain Scale button with both channel 2 Intensity Control buttons pressed to toggle on or off. The mode is saved automatically.

Battery Information

Supply Voltage Range 7.0V d.c minimum to 10V d.c. maximum

Low Voltage Indicator Threshold 7.0V d.c.

Expected Battery Life

Nominal Settings:	PPR 1, both channels on at 50% of maximum intensity
Rechargeable Battery	(Ni-Cd) 37 hours
Rechargeable Battery	(Ni-MH 150mAhr) 40 hours
Alkaline Battery	105 hours

Recommended Batteries:

Rechargeable Use Empi rechargeable battery P/N 20008 (Ni-Cd) or P/N 200030 (Ni-MH) with Empi battery charger P/N 200022. IEC - 6F22 Use a 9 Volt battery brand such as Eveready Energizer No. 522 or Varta No. 4022 IEC - 6LR61

Type BF Applied Part. Internally powered only. Ordinary protection against entry of liquids. Continuous operation.

Physical Dimensions

Size (H x W x D)	9.5cm x 6.45cm x 2.38cm (3.7in. x 2.5in. x 0.94in.)
Approx. Weight (with Ni-Cd battery)	113 grams (4.0 oz.)

Environmental Conditions

Operating Temperature	0°C to +50°C, RH 30% to 75%, 50kPa to 106kPa
Transport and Storage Temperature	-40°C to +70°C, RH 10% to 90%, 50kPa to 106kPa

Waveforms shown are typical:

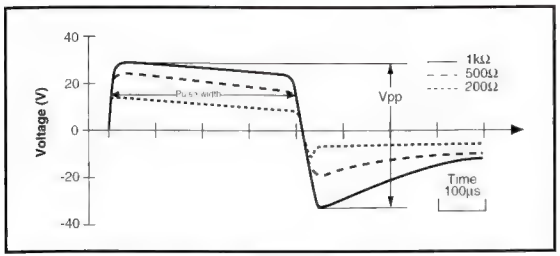


Figure A. Standard measurement output voltage across purely resistive loads at maximum High Output Intensity setting. Pulse width and Vpp measured as shown across a 1 KΩ load.

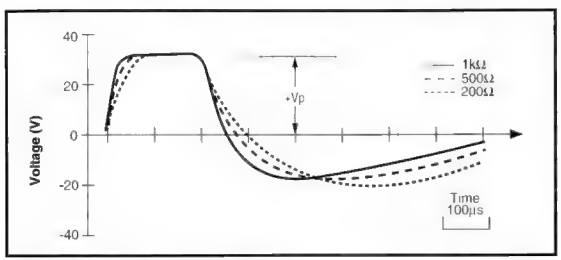


Figure B. Output voltage across AAMI loads at 50% of maximum High Output Intensity setting. Output is nominally constant voltage for intensity settings of 20 (80µs) or greater.

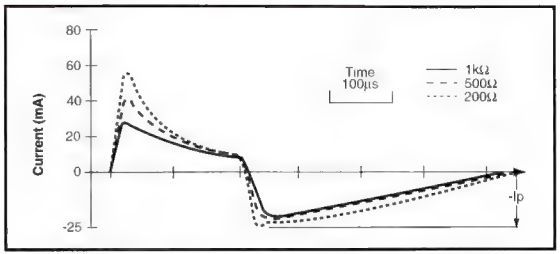


Figure C. Output current into AAMI loads at 50% of maximum High Output Intensity setting. Negative phase (undershoot) is nominally constant current.

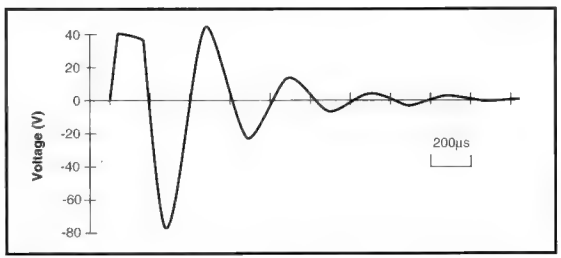


Figure D. Output voltage across a 1MΩ resistive load at 50% of maximum High Output Intensity setting.

Description of Device Markings

The markings on your Epix VT TENS device are your assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility. One or more of the following markings may appear on your device:

Council Directive 93/42/EEC Concerning Medical Devices (Medical Device Directive).

The notified body, TÜV Product Services ID 0123, has granted Empi an EC Certificate according to Annex II, Clause 3 of Council Directive 93/42/EEC.

CE 0123

CSA C22.2 No. 125-M1984
Electromedical equipment, Canadian Electrical Code.
Part II: Safety standards for Electrical Equipment Risk Class 2.

c UL Listed

Transcutaneous Electrical Nerve Stimulator
Also classified by Underwriters Laboratories Inc. in accordance with ANSI/AAMI NS4-1985 American National Standard for TENS.

UL Listed 5P42

Classified by Underwriters Laboratories Inc® with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, and CAN/CSA C22.2 No. 601.1-M90.

CLASSIFIED c UL US 11N1

Refer to ACCOMPANYING DOCUMENTS

Type BF Equipment

Limited Warranty and Disclaimer

I. Warning

While, in the opinion of Empi, Inc. ("Empi"), the use of the Epix VT Transcutaneous Electrical Nerve Stimulator (TENS) (the "Product") has met with some success in the treatment of pain, Empi makes no warranties to the purchaser as to the effectiveness of the product.

II. Warranty

A. Empi warrants to the Purchaser ("Purchaser") (and to no other person) that the Product (including any new or factory reconditioned Products, but excluding any accessories such as charger's, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream) and the component parts thereof, distributed or manufactured by Empi, shall be free from defects in the workmanship and materials for the lifetime of the Purchaser (the "Warranty Period"). The warranty Period shall be shortened, however, in the following circumstances: (i) if the Product is sold outside of the United States, the Warranty Period shall be three (3) years, (ii) if the Product is classified as a used product by a third party payer for reimbursement purposes the warranty period shall be one (1) year and (iii) if the Product does not fit under any of the previous classifications, the Warranty Period shall be one (1) year. The applicable warranty period shall be measured from the date the Product is shipped to or delivered to purchaser.

B. Accessories including, but not limited to, charger's, rechargeable batteries, electrodes, lead wires, tape adhesive patches and electrode cream are excluded from the Warranty and are sold "AS IS" because their structure is such that they may be easily damaged before or during use.

III. Limitation of Liabilities and Disclaimer of Warranties

A. Empi's sole obligation in the case of any breach of its warranties set forth in Paragraph IIA above, shall be, at Empi's option, to repair or replace the Product with a new or factory reconditioned product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Empi written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period, and within 30 days of discovery of the defect. Upon Empi's written request and authorization, Purchaser shall return the Product to Empi, freight and insurance prepaid, for inspection. Notice and return shipment shall be sent to Empi at Clear Lake Industrial Park, Clear Lake, South Dakota 57226. Purchaser may request shipment approval by calling Empi Warranty Repair Department on its toll free number 1-800-862-2343. In the case of repairs or returns outside of North America, notification and return shipment shall be sent to an Empi Authorized Service Center. To locate the appropriate service center outside of North America, contact your Authorized Empi Distributor, or contact Empi directly at 1-651-415-9000. Empi will not be responsible for damage due to improper packaging or shipment. If Empi determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Empi

will refund to the Purchaser the purchase price for the defective product, or return the repaired Product or a replacement thereof to Purchaser, freight and insurance billed to the Purchaser, as soon as reasonably possible following receipt of the Product by Empi. If Empi determines in its sole reasonable discretion that the Product does not contain defective workmanship or materials, Empi will return the Product to the Purchaser, freight and insurance billed to the Purchaser.

B. This Warranty is voided immediately as to any Product which has been repaired or modified by any person other than authorized employees or agents of Empi or which has been subjected to misuse, abuse, neglect, damage in transit, accident or negligence.

C. EXCEPT AS PROVIDED IN PARAGRAPH IIA, THE PRODUCT IS BEING SOLD ON AN "AS IS" BASIS, ALL ACCESSORIES ARE SOLD "AS IS", AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PRODUCT IS WITH PURCHASER. THE WARRANTY PROVIDED IN PARAGRAPH IIA IS INTENDED SOLELY FOR THE BENEFIT OF THE INITIAL PURCHASER AND EMPI DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE; PROVIDED, HOWEVER, THAT NOTWITHSTANDING THE FOREGOING SENTENCE, IN THE EVENT AN IMPLIED WARRANTY IS DETERMINED TO EXIST, THE PERIOD FOR PERFORMANCE BY EMPI THEREUNDER SHALL BE LIMITED TO THE LIFETIME OF THE INITIAL PURCHASER. NO EMPLOYEE, REPRESENTATIVE OR AGENT OF EMPI HAS ANY AUTHORITY TO BIND EMPI TO ANY AFFIRMATION, REPRESENTATION OR WARRANTY EXCEPT AS STATED IN THIS WRITTEN WARRANTY POLICY.

(This Warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how long an implied warranty lasts, so the above limitation may not apply to the Purchaser.)

D. EMPI SHALL NOT BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, LOST PROFITS OR MEDICAL EXPENSES CAUSED BY ANY DEFECT, FAILURE, MALFUNCTION OR OTHERWISE OF THE PRODUCT, REGARDLESS OF THE FORM IN WHICH ANY LEGAL OR EQUITABLE ACTION MAY BE BROUGHT AGAINST EMPI (E.G. CONTRACT, NEGLIGENCE OR OTHERWISE) THE REMEDY PROVIDED IN PARAGRAPH IIIA ABOVE SHALL CONSTITUTE PURCHASER'S SOLE REMEDY. IN NO EVENT SHALL EMPI'S LIABILITY UNDER ANY CAUSE OF ACTION RELATING TO THE PRODUCT EXCEED THE PURCHASE PRICE OF THE PRODUCT.

(This Warranty gives Purchaser specific legal rights and Purchaser may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to the Purchaser.)

Notes

Your authorized representative:

Empi
599 Cardigan Road
St. Paul, Minnesota 55126-4099 USA
1-651-415-9000; 1-800-328-2536